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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/807,809

Applicant(s)

POSSEE ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 30 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 27-50 are pending in this application.

### **Sequence Compliance**

This application contains sequence disclosures that are encompassed by the definitions for nucleotides and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).

Specifically, there are sequences disclosed in Table 2, page 14, and Table 3, page 19, page 22, page 23 and page 31 that do not have SEQ ID numbers associated with them.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Blissard et al. US patent 5,750,383 (May 12, 1998).

Blissard et al. teach use of a novel baculovirus cloning system in which an essential gene for replication is removed from or inactivated from the viral genome. Cells are transfected with

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a plasmid that contains the essential gene linked to a foreign gene. Thus the baculovirus is rescued and able to propagate normally (abstract). The essential genes include the immediate early genes (*ie*), *ie-1* and the *lef* genes (column 13, line 15-18).

Claims 27-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark et al. US patent 6,225,060 B1 (May 1, 2001).

Clark et al. teach use of a baculovirus vector for expression of genetic material. As shown in figure two, the method involves cloning of a cDNA of interest by presenting an insect cell with a baculovirus DNA deleted of p35 and orf-1629 with a linear DNA comprised of baculovirus DNA and a p35 gene and a orf-1629 gene. Co-transfection yielded recombinant baculovirus in a process that did not utilize cloning steps (column 5, line 1-7).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. in view of Nasmyth et al.

Applicants claim a method of cloning a gene comprising the steps of providing a replication-deficient baculovirus vector and a "rescue" vector encoding a nucleic acid that restores replication and a transgene. Functional genes are lacking the baculovirus vector such as

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lef genes and *ie*. The vector is furthermore capable of being maintained in an intermediate host such as yeast or bacteria.

Clark et al. teach use of a baculovirus vector for expression of genetic material. As shown in figure two, the method involves cloning of a cDNA of interest by providing an insect cell with baculovirus DNA deleted of p35 and orf-1629 and a linear DNA comprised of baculovirus DNA and a p35 gene and a orf-1629 gene. Co-transfection yields recombinant baculovirus without utilizing cloning steps (column 5, line 1-7). Clark et al do not teach the use of a baculovirus vector that can replicate in yeast cells as well as insect cells.

Nasmyth et al. teaches use of a baculovirus vector that can replicate in *Saccharomyces cerevisiae* as well as insect cells. A shuttle vector YCbv was generated that could be used to grow in bacteria and yeast and could be used as a recipient of transgene insertion through homologous recombination (page 100, column 1, line 1-8). Nasmyth does not teach a replication defective baculovirus whose replication function is provided in trans by the transgene-carrying vector. Nasmyth and Clark are analogous art as both are improved methods for gene cloning utilizing baculovirus as a vector.

One of ordinary skill would have been motivated to use the method of Nasmyth et al. to clone the baculovirus of Clark et al. for the expected benefit of reducing time consumption (Nasmyth, page 97, column 2, third paragraph) and reducing cost due to the lack of need for rounds of plaque purification and the ability to isolate multiple recombinants simultaneously (Nasmyth et al, page 103, column 2, first paragraph). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Clark et al. with the methods of Nasmyth et al. by the addition of yeast selectable markers to the baculovirus of

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Clark et al. such that a baculovirus vector that can replicate in yeast is produced. Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-34 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of *lef1-12*, *dnapol*, *pl43*, *p35*, *ie-1*, *p47*, *ORF1629* and *pp31* genes and functional fragments or mutations thereof.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed

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correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants only disclose *lef-2* but do not disclose functional fragments or mutations thereof. The prior art only teaches functional fragments through mutational analysis of the *ie-2* gene. Given the large size and diversity of the Baculovirus family (hundreds of different viruses), the diversity of the recited genes, the absence of disclosed or art recognized correlations between structure and function and the large number of potential fragments and mutations, it must be considered that any functional fragment or mutation must be empirically determined. By disclosing *lef-2*, the applicants have not reduced to practice the claimed invention and the relationship between structure and function is unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Claims 27-50 are rejected.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

December 16, 2002

DAVID GUZO  
PRIMARY EXAMINER  
